

Federal Communications Commission

FCC 00-211

FCC MAIL SECTION

Before the
Federal Communications Commission
Washington, D.C. 20554

JUN 15 3 55 PM '00

In the Matter of

Amendment of Parts 2 and 95 of
the Commission's Rules to Create a
Wireless Medical Telemetry Service

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ET Docket 99-255

PR Docket 92-235 ✓

REPORT AND ORDER
(proceeding terminated)

Adopted: June 8, 2000

Released: June 12, 2000

By the Commission:

I. INTRODUCTION

1. By this action, the Commission establishes a new Wireless Medical Telemetry Service (WMTS) which will enhance the ability of health care providers to offer high quality and cost-effective care to patients with acute and chronic health care needs. This action addresses consumer concerns that medical telemetry devices are increasingly at risk of harmful interference due to more extensive use of spectrum resources by other applications. The Commission allocates 14 Megahertz (MHz) to WMTS on a primary basis, which will allow potentially life-critical medical telemetry equipment to operate on an interference-protected basis. The Commission also adopts service rules for WMTS that "license by rule" to minimize regulatory procedures to facilitate rapid deployment. Medical telemetry equipment is used in hospitals and health care facilities to transmit patient measurement data, such as pulse and respiration rates to a nearby receiver, permitting greater patient mobility and increased comfort. As this service permits remote monitoring of several patients simultaneously it could also potentially decrease health care costs. The Commission's action will improve the reliability of this vital service.

II. BACKGROUND

2. Previously, medical telemetry devices were only allowed to operate under either Part 15 or Part 90 of the Commission's rules. Part 15 of the rules permitted medical telemetry equipment to operate on an unlicensed basis on vacant Television (TV) channels 7-13 and 14-46 (174-216 MHz and 470-668 MHz).¹ Part 90 of the rules permitted medical telemetry equipment to operate on a secondary² basis to land mobile users in the 450-470 MHz band.³ Medical telemetry has no protection from interference from the primary users of these bands.

¹ See 47 C.F.R. § 15.242.

² See *Replacement of Part 90 by Part 88 to Revise the Private Land Mobile Radio Services and Modify the Policies Governing Them and Examination of Exclusivity and Frequency Assignment Policies of the Private Land*

3. The spectrum used by medical telemetry equipment on an unlicensed or secondary basis under Parts 15 and 90 is increasingly being used more intensively by existing primary services, thereby posing an increased risk of interference to medical telemetry devices. In 1995, the Commission adopted changes to Part 90 of the rules to allow for more efficient use of the spectrum by land mobile services. These changes established a new channeling plan for private land mobile radio (PLMR) services in the 450-470 MHz band by decreasing the channel spacing from 25.0 kHz to 6.25 kHz.⁴ Under the new channeling scheme, high-power primary users of the band would be able to operate on the low power "offset" channels used by medical telemetry equipment.⁵ This could result in interference to medical telemetry equipment, possibly causing it to be unusable at times. For this reason, the Commission placed a freeze on the filing of applications for high power operation in the 450-470 MHz band on the offset channels in 1995, which remains in effect pending the development of a plan to protect low power operations in this band.⁶

4. In addition to the above-mentioned Part 90 rule changes, there have been other recent changes to the Commission's rules that could result in harmful interference to medical telemetry equipment operating under Part 15. At the direction of Congress, the Commission has provided for the introduction of digital television (DTV) stations in the TV broadcast bands.⁷ In order to accomplish this, the Commission has provided each local TV station with an additional 6 MHz channel that will be used to broadcast DTV during the transition.⁸ This means that there will be fewer vacant channels in every market, and that in some areas, channels that were once unused for TV broadcasting may now be used for analog DTV.

5. The transition from analog to digital television is currently under way, with the first stations commencing DTV broadcasting in November 1998. The Commission has created over

Mobile Radio Services, PR Docket 92-235, Report and Order and Further Notice of Proposed Rule Making (Refarming R&O), 10 FCC Rcd 10076 (1995). Medical telemetry equipment operates on the Part 90 channels that were designated as low power offset channels under Section 90.267. Prior to the adoption of the Refarming R&O, operation on all of these channels was on a secondary basis to the high power channels operating 12.5 kHz away. In the Refarming R&O a mechanism was provided whereby devices operating on those channels could operate under primary status contingent on the replacement of existing equipment with equipment designed to operate on channels of 12.5 kHz or less. Because the vast majority, if not all, of the existing installed base of medical telemetry equipment is designed to operate with a channel bandwidth of 25 kHz, these devices continue to operate with secondary status.

³ See 47 C.F.R. §§ 90.238 and 90.267.

⁴ See Refarming R&O.

⁵ Under the old Part 90 channeling scheme, medical telemetry equipment operated on special channels offset 12.5 kHz from the center frequency of the primary 25.0 KHz channels. This frequency offset, combined with the lower power limit on these channels minimize the possibility of interference caused or received by medical telemetry equipment.

⁶ See Public Notice, "Freeze on the Filing of High Power Applications for 12.5 kHz Offset Channels in the 450-470 MHz Band," released August 11, 1995, 10 FCC Rcd 9995 (1995). On June 4, 1997, the Land Mobile Communications Council (LMCC), an umbrella organization that includes frequency coordinators for the PLMR services, submitted a proposed plan that would protect low power operation on the 12.5 kHz offset channels. The Commission has not approved the plan, so the freeze on high power applications remains in effect.

⁷ Advanced Television Systems and Their Impact upon the Existing Television Broadcast Service, MM Docket 87-268, Sixth Report and Order, 12 FCC Rcd 14588 (1997).

⁸ Id. 12 FCC Rcd at 14595.

1,600 allotments for DTV stations, a large percentage of which are on TV channels 7-46, which are also used for medical telemetry equipment operating under Part 15 of the rules.⁹ All television stations are required to commence DTV broadcasting no later than May 1, 2003.¹⁰ As existing stations begin DTV operation on their new channels, some low-power television stations currently operating on or adjacent to those channels may be forced to switch frequencies to avoid causing harmful interference to DTV, further crowding the spectrum used by medical telemetry equipment.¹¹

6. Concerns about possible interference to medical telemetry equipment by DTV operations were heightened in March 1998 when a TV station in Texas began test transmissions on a previously unused channel that had been assigned to it for DTV operation. The transmissions caused severe interference to the operation of medical telemetry equipment at a nearby hospital, rendering the equipment temporarily unusable. The station immediately ceased operation upon learning of the interference, and the medical telemetry equipment was changed to operate on another frequency. The Commission and the Food and Drug Administration (FDA) have since taken steps to help ensure that hospitals are notified before new DTV stations come on the air to provide them with time to modify any medical telemetry equipment that operates on the same frequency.¹²

7. In the *Notice of Proposed Rule Making* in this proceeding, we proposed to allocate spectrum where medical telemetry equipment could operate on a primary basis.¹³ We also proposed to establish a new Wireless Medical Telemetry Service (WMTS) under Part 95 of the rules. The Commission's proposal was based on recommendations provided by the American Hospital Association's (AHA) Medical Telemetry Task Force, which was established in coordination with the FDA, in response to the incidence of interference to medical telemetry equipment from a DTV station described above. A total of 33 parties filed comments in response to the *Notice*, and 9 parties filed reply comments. The vast majority of comments supported the Commission's proposal to establish a WMTS, and a number of parties provided recommendations to improve the proposals in the *Notice*.

⁹ See 47 C.F.R. § 73.622.

¹⁰ See 47 C.F.R. § 73.624(d). All network affiliated stations in the top ten television markets were to commence DTV broadcasts by May 1, 1999. All network affiliated stations not included in this category and in the top 30 television markets were to commence DTV broadcasts by November 1, 1999. The deadline for all remaining commercial stations is May 1, 2002, and the deadline for all noncommercial stations is May 1, 2003.

¹¹ Low power television stations under Part 74 of the rules operate on a secondary basis to full power television stations. See 47 C.F.R. § 74.701, *et. seq.*

¹² See *Joint Statement of the Federal Communications Commission and the Food and Drug Administration Regarding Avoidance of Interference Between Digital Television and Medical Telemetry Devices*, released March 25, 1998 and *Office Of Engineering And Technology Fact Sheet, Sharing of Analog and Digital Television Spectrum by Medical Telemetry Devices*, dated March 1998. Copies of these documents are available from the Commission's Internet site at <http://www.fcc.gov/healthnet/dtv.html>.

¹³ Amendment of Parts 2 and 95 of the Commission's Rules to Create a Wireless Medical Telemetry Service, *Notice of Proposed Rule Making*, ET Docket 99-255, 14 FCC Rcd 16719 (1999).

III. DISCUSSION

A. Spectrum Allocation

1. Spectrum Requirements

8. The *Notice* proposed to allocate 14 MHz of spectrum to the WMTS. This proposal was based on an AHA survey of hospitals of various sizes in both metropolitan and suburban/rural areas to determine the amount of spectrum needed for medical telemetry equipment. In order to calculate the amount of spectrum required, AHA assumed six categories of patient medical parameters that would be measured and that the transmitters could operate with a spectral efficiency of 0.8 bits per second per Hertz (bps/Hz), which is approximately the same spectral efficiency the Commission requires in Part 90 of the rules.¹⁴ AHA determined that a total of 6.125 MHz is required to meet current patient needs and that the spectrum requirements for medical telemetry equipment would likely double within ten years, resulting in a requirement of at least 12 MHz of spectrum for medical telemetry equipment.¹⁵

9. CDRH, IIT and Brian Porras agreed with the AHA recommendation for the amount of spectrum required.¹⁶ IIT stated that the methodology used by AHA to estimate current and future spectrum needs is sound, and Brian Porras stated that 12 MHz of spectrum is necessary because spectrum needs will increase dramatically in the future.¹⁷ Spacelabs believes that the assumed spectral efficiency of 0.8 bps/Hz is not currently achievable, but could be in about two years, while Zymed believes that a 0.4 bps/Hz spectral efficiency is more reasonable.¹⁸ Datex-Ohmeda and Mortara both believe that more spectrum will be required. Datex-Ohmeda states that 30 MHz will be needed for a hospital with 200 monitored patients.¹⁹ Mortara states that 12 lead electrocardiograms (ECGs) require significantly greater bandwidth than 6 MHz, and that the proposed amount of spectrum is based on the technology of the last 20 years and will not be adequate for the next 20 years.²⁰ However, Final Analysis and PCIA both disagree with allocating 12 MHz of spectrum for medical telemetry. Final Analysis claims that 12 MHz was based on a survey biased to give inflated results, then doubled to estimate future growth.²¹ PCIA questions the need for 12 MHz of spectrum, stating that there has been an inadequate demonstration of a need sufficient to warrant double the amount of spectrum allegedly required today at the largest institutions.²² ACCE disagrees with Final Analysis that the proposed 14 MHz allocation is wasteful

¹⁴ See 47 C.F.R. §§ 90.203(j)(3) and 90.203(j)(5). These sections require a spectral efficiency of 4,800 bits per second per 6.25 kHz, which corresponds to 0.768 bits per second per hertz.

¹⁵ See AHA report at 10.

¹⁶ See CDRH comments at 3, IIT comments at 1, and Brian Porras comments at 1.

¹⁷ See IIT comments at 1 and Brian Porras comments at 1.

¹⁸ See Spacelabs comments at 5 and Zymed comments at 2.

¹⁹ See Datex-Ohmeda comments at 1.

²⁰ See Mortara comments at 2.

²¹ See Final Analysis comments at 16.

²² See PCIA comments at 4.

and unwarranted, stating that the AHA survey of hospitals documented the need in a reasonable and methodical manner.²³

10. The AHA study cited a need for 6 MHz now and at least 12 MHz in the near future of interference-free spectrum to satisfy the nation's needs for safe and reliable wireless medical telemetry capabilities.²⁴ We find this estimate is reasonable. As the Department of Health and Human Services notes, it is likely that the use of medical telemetry will become more widespread, driven by the need to reduce medical care costs and by increasing advances in medical technology. Medical telemetry devices can reduce health care costs by helping to speed the patient recovery time and reduce the duration of hospital stays. Advances in medical technology will allow monitoring of an increasing number of patient parameters, which will increase spectrum requirements. We also note that demand is likely to be influenced by the growing population of elderly people in the United States. We do not concur with Final Analysis, which states that the AHA survey is based on inflated spectrum requirements, which were then doubled to estimate future growth. Nor do we agree with PCIA, which questions the need for 12 MHz and notes that this amount is over double the amount of spectrum currently required by the largest institutions. As noted by the American College of Clinical Engineering, the AHA results were based on a study of more than a half dozen clinical organizations and fourteen geographically dispersed hospitals of various sizes. We do believe, however, that the estimate of Datex-Ohmeda that 30 MHz of spectrum will be required for 200 patients appears excessive, because 150 kHz channels for data transmission should not be required if efficient modulation techniques are employed. Hence, we accept assertions of the medical community that the number of parameters being monitored using medical telemetry will increase in the future and support the AHA findings on spectrum requirements.

11. We are making available 14 MHz of spectrum in three blocks located at 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz for wireless medical telemetry. In making available 14 MHz of spectrum, we note that these bands each have significant constraints, such that the entire allocation is unlikely to be available in any individual market. The 608-614 MHz band is constrained as a result of radio astronomy quiet zones, including some sites in large markets, and interference from adjacent TV channels.²⁵ The remaining 8 MHz that we are allocating is constrained by adjacent band interference from high power radars located below 1390 MHz and grandfathered protected Federal sites.²⁶ However, this allocation ensures that at least 6 MHz is available for WMTS in all locations, consistent with the AHA needs assessment, with at least some additional spectrum available to accommodate long term needs. We note that this is in fact significantly less than the amount of spectrum that is currently available to medical telemetry on an unprotected basis.²⁷ However, we find that the benefits of a primary allocation dedicated to this service compensates for the reduced availability of spectrum. We wish to underscore that we do not anticipate any further allocations for medical telemetry devices and expect manufacturers and the health care community to ensure that this spectrum is used efficiently to meet long term needs. We also wish to note that this medical telemetry allocation is

²³ See ACCE reply comments at 2.

²⁴ See AHA comments at 10.

²⁵ See AHA reply comments at 7 and GE Marquette Medical Systems, Inc at 6.

²⁶ See *supra* 31.

²⁷ See 47 C.F.R. § 15.242.

an exception to the approach we have been taking toward more flexible allocations that are not service specific. A specific allocation is necessary in this case to protect the public safety by providing spectrum where medical telemetry equipment can operate without interference. Further, it will resolve conflicts that have delayed the land mobile refarming and that are affecting the deployment of DTV.

2. Frequency Bands

12. The *Notice* proposed the following two options for frequency bands to be allocated to the WMTS:

Option 1

608-614 MHz
1395-1400 MHz
1429-1432 MHz

Option 2

608-614 MHz
1391-1400 MHz

13. The 608-614 MHz band corresponds to TV channel 37, which is not used for TV stations and is currently reserved for radio astronomy. It is available for medical telemetry under Part 15 of the rules on an unlicensed basis.²⁸ The other proposed bands are former government bands that were reallocated for non-government use under the Omnibus Budget Reconciliation Act of 1993.²⁹ Government operations in those bands may continue at certain sites around the country for a number of years.³⁰

14. Two different options were proposed because other parties had expressed an interest in operating in portions of the 1300 MHz and 1400 MHz bands. For example the Land Mobile Communications Council (LMCC) has filed a petition for rule making to allocate the 1390-1400 MHz and 1427-1432 MHz bands for private land mobile services under Part 90 of the rules.³¹ Itron, Inc. filed a petition for rule making on February 29, 2000 requesting that the Commission allocate the 1427-1432 MHz band for utility telemetry on a primary basis.³² In addition, several licensees of low earth orbit ("Little Leo"³³) satellite systems have been performing studies on the feasibility of operating satellite feeder uplinks in the 1390-1393 MHz band and downlinks in the 1429-1432 MHz band as part of an effort to obtain an international frequency allocation for this purpose.³⁴

²⁸ See 47 C.F.R. § 15.242.

²⁹ See Pub. L. No. 103-66, 107 Stat. 312 (1993).

³⁰ Government operations may continue in the 1390-1400 MHz band at 17 sites around the country until the year 2009. These sites are listed in United States footnote US351 in Appendix A. Government operations may continue in the 1427-1432 MHz band at 14 sites around the country until the year 2004. Those sites are listed in United States footnote US352 in Appendix A.

³¹ See Land Mobile Communications Council Petition for Rule Making, dated April 22, 1998, RM-9267.

³² RM-9854. Itron is currently licensed to operate utility telemetry on a secondary basis in this band.

³³ "Little Leo" systems provide data-only Mobile Satellite Service via a constellation of non-geostationary orbit satellites operating below 1 GHz.

³⁴ See Final Analysis comments at 11-15.

15. AHA, Brian Porras, MedStar, Spacelabs and Vitalcom support frequency option 1 because the split upper bands will facilitate two-way communications.³⁵ AHA does not believe it is possible to share the 1429-1432 MHz band with Little Leo satellite systems, and it recommends allocating this band for medical telemetry even though it would preclude its use for Little Leo feeder downlinks.³⁶ AHA states there is no guarantee that the band would ever be allocated internationally for Little Leos, so the Commission should allocate it for medical telemetry, which has a current substantiated need.³⁷ CDRH is concerned that co-primary status for Little Leos and WMTS could result in interference to medical telemetry.³⁸ IIT Research believes that WMTS is unlikely to cause interference to Little Leos, but Little Leos could cause interference to WMTS.³⁹ MedStar suggests that the Commission find an alternative to the 1429-1432 MHz band because sharing with Little Leo downlinks is unlikely.⁴⁰ NTIA supports proposed frequency Option 1 since it provides increased spectrum flexibility over the bands proposed in Option 2.⁴¹ The National Academies support Option 1 because it will have less impact on sensitive radio astronomy operations.⁴²

16. ORBCOMM prefers frequency Option 2 (608-614/1391-1400 MHz) because there would be only 2 MHz of overlap with the prospective Little Leo uplink frequencies and no overlap with the prospective downlink frequencies.⁴³ It believes that sharing between Little Leos and medical telemetry is possible in both the prospective uplink and downlink bands. ORBCOMM assumes that medical telemetry equipment will be used indoors, so it will not receive interference on the downlink frequencies, and the uplinks can be located in remote areas to minimize the possibility of interference to medical telemetry.⁴⁴ IIT states that there is no inherent technical advantage to WMTS from either of the frequency options proposed by the Commission. It believes that WMTS is unlikely to cause interference to Little Leos, but Little Leo operations could cause interference to medical telemetry.⁴⁵

17. Itron opposes allocating the 1429-1432 MHz band for medical telemetry, stating that the *Notice* does not consider the impact on their meter reading systems in the 1427-1432 MHz band, and that medical telemetry equipment in the band could jeopardize continued operation of meter-reading services.⁴⁶ It notes that the comments in this proceeding do not resolve the question of whether medical telemetry equipment can share the 1429-1432 MHz band with meter reading equipment, and it urges the Commission not to allocate that band for medical telemetry, or at least

³⁵ See AHA comments at 9, Brian Porras comments at 2, MedStar comments at 8, Spacelabs comments at 3, and Vitalcom comments at 7.

³⁶ See AHA comments at 9-11 and AHA reply comments at 9-10.

³⁷ See AHA reply comments at 10.

³⁸ See CDRH comments at 4.

³⁹ See IIT comments at 3.

⁴⁰ See MedStar comments at 8.

⁴¹ See NTIA comments at 1.

⁴² See National Academies comments at 3-4.

⁴³ See ORBCOMM comments at 5.

⁴⁴ See ORBCOMM comments at 6-7.

⁴⁵ See IIT comments at 3.

⁴⁶ See Itron comments at 2-3.

explore interference issues thoroughly.⁴⁷ Final Analysis opposes both proposed options for medical telemetry frequency bands. It states that the Commission should consider other alternatives for satisfying the needs of the WMTS without harming Little Leos, and that neither option is suitable due to the difficulties in sharing spectrum between Little Leos and medical telemetry. Final Analysis further states that the Commission may not remove spectrum from the reserve⁴⁸ unless or until a determination has been made that it can be replenished. It also contends that the Commission could allocate frequencies in the bands 1385-1390 MHz and 1432-1435 MHz without the need for auction, or alternatively the Commission could allocate frequencies in the bands 1394-1400 MHz or 1427-1429 MHz.⁴⁹

18. We conclude that it is necessary to allocate spectrum where medical telemetry equipment can operate on a primary basis. Based on the record, we also conclude that WMTS's planned use is best accommodated by making three blocks of spectrum in the 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz bands as discussed below.⁵⁰

19. 608-614 MHz. We find the 608-614 MHz band to be suitable for WMTS because, other than radio astronomy, it is only used for medical telemetry under Part 15 of the rules. We also note that no commenters opposed the use of this band. Accordingly, we allocate this band to medical telemetry equipment on a co-primary basis with radio astronomy. Operation of medical telemetry equipment in this band must not cause interference to sensitive radio astronomy operations, and users will be required to coordinate their operation with radio astronomy facilities.⁵¹ We note that medical telemetry service providers operating on 608-614 MHz (television channel 37) currently must accept adjacent channel interference from broadcast television stations operating on channels 36 and 38. With this allocation, we are not requiring television broadcasters to protect WMTS from adjacent band interference. We believe that the multi-band approach that we are adopting provides sufficient flexibility to WMTS. WMTS providers can operate on one of the other bands that we are making available in situations where a hospital is in close proximity to a television station operating on channels 36 or 38. Furthermore, WMTS providers can design equipment to provide sufficient protection from adjacent channel interference as is current practice.

20. 1395-1400 MHz and 1429-1432 MHz. In addition to the 608-614 MHz band, we are allocating the 1395-1400 MHz and 1429-1432 MHz bands for medical telemetry. Allocating the 1395-1400 MHz band instead of the alternative band we proposed will result in a 4 MHz greater frequency separation between medical telemetry and government radars operating below 1385 MHz, thereby reducing the risk of interference to medical telemetry equipment. We find that the

⁴⁷ See Itron reply comments at 1-2.

⁴⁸ The Omnibus Budget Reconciliation Act of 1993 required the transfer of at least 200 MHz of spectrum from government to non-government use. The Act required a significant portion of that spectrum to be held in reserve until after a ten-year period. The Commission placed 65 MHz of the transferred spectrum in reserve in the following bands: 1390-1400 MHz, 1427-1432 MHz, 1670-1675 MHz and 1710-1755 MHz. See Plan for Reallocated Spectrum, 11 FCC Rcd 17841 (1999).

⁴⁹ See Final Analysis comments at 20-27.

⁵⁰ We will coordinate the frequency allocations with Canadian and Mexican governments as appropriate. Given the low-power nature of this equipment, we do not anticipate any interference issues in border areas.

⁵¹ See footnote US 246 to the Table of Allocations in Appendix A.

frequency separation between the 1395-1400 MHz and the 1429-1432 MHz bands will give greater flexibility for medical telemetry by making the bands more useful for two-way communications than a single contiguous band at 1391-1400 MHz.

21. We understand that Little Leo operators seek more spectrum for feeder links and have expressed interest in the 1429-1432 MHz band. The Little Leo industry is currently conducting studies on the feasibility of additional feeder links in this band.⁵² We note that a domestic allocation for Little Leo feeder links would be of little value without an international allocation due to the international nature of this service. We recognize that the recently completed World Radiocommunications Conference adopted a resolution calling for tests and demonstrations to validate sharing between Little Leos' feederlinks and existing and planned services in the 1390-1393 MHz and 1429-1432 MHz bands.⁵³ We also recognize that allocating the 1429-1432 MHz band for medical telemetry may limit possible use of the this band in the United States by Little Leos due to likely sharing constraints. As medical telemetry has an immediate need for new spectrum, we conclude that 1429-1432 MHz should be made available for WMTS at this time and this allocation should be considered in forthcoming sharing feasibility analyses. The other bands recommended by Final Analysis for medical telemetry are simply not suitable. The 1385-1390 MHz band has been reallocated back to government use,⁵⁴ the 1427-1429 MHz band is already heavily used for utility telemetry equipment and we have not yet determined whether sharing between medical telemetry and utility telemetry is possible. Further, NTIA notes that the 1432-1435 MHz band was transferred to the Commission for assignment to new services by competitive bidding pursuant to the Balanced Budget Act of 1997.⁵⁵ We disagree with Final Analysis' contention that spectrum placed in the reserve can not be removed until a replacement has been designated. The Omnibus Budget Reconciliation Act of 1993 which directed the Commission to establish a spectrum reserve does not specify a specific amount that must be held in reserve, and it states that the Commission is not precluded from making changes to the spectrum use plan it develops.⁵⁶ The Commission previously noted that it would be open to petitions to use the 1390-1400 MHz and 1427-1432 MHz bands prior to the date when allocation of the remaining spectrum in the reserve begins.⁵⁷

22. As stated above, both LMCC and Itron have filed petitions for rule making to allocate the 1429-1432 MHz band for other purposes.⁵⁸ We find that medical telemetry has an immediate need for new spectrum, and that this band is suitable for medical telemetry. This action does not foreclose LMCC or Itron from obtaining new spectrum allocations. As we stated in our November 1999 *Policy Statement*, the bands 1390-1395 MHz, 1427-1429 MHz and 1432-1435 MHz could be used for land mobile services.⁵⁹ In addition, the band 1427-1429 MHz could be used for utility

⁵² See *Final Analysis* comments at 13.

⁵³ See RESOLUTION 127 (Rev. WRC-2000), The World Radiocommunications Conference (Istanbul, 2000).

⁵⁴ See Section 1062 of the National Defense Authorization Act for Fiscal Year 2000, Public Law 106-65 (1999).

⁵⁵ See *NTIA* comments at 2.

⁵⁶ See 47 U.S.C. § 925(b).

⁵⁷ See *Principles for Reallocation of Spectrum to Encourage the Development of Telecommunications Technologies for the New Millennium, Policy Statement*, 11 FCC Rcd 17841(1996) at para. 65.

⁵⁸ The 1427-1435 MHz band is currently available for Part 90 operation on a secondary basis.

⁵⁹ See *Principles for Reallocation of Spectrum to Encourage the Development of Telecommunications Technologies for the New Millennium, Policy Statement*, 14 FCC Rcd 19868 (1999) at para. 24.

telemetry, and it may be possible to share the 1429-1432 MHz band between utility telemetry and medical telemetry.⁶⁰ Accordingly, we will consider the LMCC and Itron petitions in separate proceedings.

B. Service Rules

23. In this section, we adopt service rules for the new Wireless Medical Telemetry Service (WMTS). These service rules only apply to the WMTS that will operate at 608-614 MHz, 1395-1400 MHz, and 1429-1432 MHz, and not to the current medical telemetry operations permitted under Parts 15 and 90. The rules include licensing requirements and technical standards for the equipment, as well as a frequency coordination procedure.

24. Definition. In the *Notice*, we proposed the following definition for medical telemetry:

Wireless medical telemetry is defined as the measurement and recording of physiological parameters and other patient-related information via radiated bi- or unidirectional electromagnetic signals.⁶¹

25. Final Analysis states that the definition of medical telemetry should exclude video and voice transmissions, and that medical telemetry should be limited to uni-directional transmissions on a primary basis, with bi-directional transmissions having secondary status.⁶² AHA disagrees that bi-directional transmissions should be secondary, stating that bi-directional transmissions are already used for telecommand, power control and retransmission functions by medical telemetry equipment operating in the ISM bands under Part 15.⁶³ Allowing bi-directional functions will promote the most efficient and cost-effective use of the new WMTS spectrum and advance the development of higher quality WMTS systems.⁶⁴

26. We agree that allowing bi-directional transmissions could promote the development of more advanced medical telemetry equipment and encourage more efficient use of the spectrum. The split frequency allocation we are adopting in this item was selected in part to facilitate two-way communications. Accordingly, we are adopting a definition of medical telemetry that will allow bi-directional transmissions. We find it unnecessary to exclude voice and video transmissions in the definition for medical telemetry. The issue of the types of communications that will be permitted in the WMTS is discussed below.

⁶⁰ The Itron petition requesting an allocation of the 1427-1432 MHz band for automatic meter reading and utility telemetry use was placed on Public Notice by the Commission on April 20, 2000. On June 1, 2000, Itron and the American Hospital Association jointly filed a letter stating that both parties agree that sharing between medical telemetry and utility telemetry will be possible because the technologies are compatible. We will consider the Itron and LMCC petitions in a future comprehensive proceeding to allocate the remaining government transfer spectrum in the 1390-1400 MHz and 1427-1435 MHz bands.

⁶¹ See Notice at para. 25.

⁶² See Final Analysis comments at 32.

⁶³ See AHA reply comments at 13. Medical telemetry equipment can operate in certain ISM bands under Part 15 of the rules. See 47 C.F.R. §§ 15.247 and 15.249.

⁶⁴ See AHA reply comments at 13.

27. Licensing. There were no comments opposing our proposal that WMTS equipment be "licensed by rule", rather than requiring individual operators' licenses. Individual licensing is generally designed to give a licensee a protected service area, and thus establishes rights among competing entities in the same service. Operators in the WMTS will not be in competition with each other as are parties in other radio services. The WMTS spectrum will be shared among medical telemetry users, and there will be no mutual exclusivity between users. In addition, "licensing by rule" will minimize regulatory procedures and thus facilitate deployment. We are therefore adopting our proposal that the WMTS exist as one of the Citizen's Band services contained in Part 95 of the rules and that the equipment used in this service be "licensed by rule".⁶⁵ The Commission has authority under Section 307(e) of the Communications Act to define the citizen's band radio services and to license them by rule.⁶⁶

28. Eligibility. We proposed that only authorized health care providers be eligible to operate transmitters in the WMTS. For the purpose of this service, an "authorized health care provider" would be defined as 1) a physician or other individual authorized under state or federal law to provide health care services; 2) a health care facility operated by or employing individuals authorized under state or federal law to provide health care services; or 3) any trained technician under the supervision and control of an individual or health care facility authorized under state or federal law to provide health care services.⁶⁷ We proposed to define a "health care provider facility" as a hospital or other establishment that offers services, facilities and beds for use beyond a 24 hour period in rendering medical treatment, and organizations regularly engaged in providing medical services through clinics, public health facilities and similar establishments, including government entities and agencies such as Veterans Administration Hospitals. Health care facilities on tribal lands would also be included under our proposed definition. A health care facility would not include an ambulance or other moving vehicle, and this definition would also not allow home use of WMTS equipment.⁶⁸ We are adopting these eligibility definitions as proposed.

29. Final Analysis believes that the definition of a health care facility should be limited to facilities accredited under state or federal law to more clearly identify the limits on medical telemetry.⁶⁹ AHA disagrees with Final Analysis, stating that not only do some hospitals operate without accreditation, but accreditation is provided by private parties and not under state or federal law.⁷⁰ We find that this proposed change to the definition of health care facility would be unreasonably restrictive, and we are not adopting it.

30. OAT disagrees with our proposed prohibition on using equipment in an ambulance or other moving vehicle, because paramedics are or will be important users of telemetry and other wireless technology. OAT believes the FCC should expand the eligibility definition of medical telemetry to cover home uses because home medical care may become one of the fastest growing segments of the health care industry in the future.⁷¹ Spacelabs and Zymed also believe the eligibility

⁶⁵ See 47 C.F.R. § 95.401 et. seq.

⁶⁶ See 47 U.S.C. § 307(e)(1) and (3).

⁶⁷ See Notice at para. 28.

⁶⁸ Id.

⁶⁹ See Final Analysis comments at 33.

⁷⁰ See AHA reply comments at 12-13.

⁷¹ See OAT comments at 1-2.

requirements for WMTS should be extended to allow home use. Zymed believes that home use of WMTS should be permitted since there is a trend toward home health care, and Spacelabs states that home care telemetry monitoring will be technically feasible and practical in the near future.⁷² ACCE believes that the Commission should allow for expansion of WMTS to the home due to the rate of increase of patient needs for home health care and the expanding applications of WMTS technology.⁷³ However, Vitalcom opposes the in-home use of WMTS at this time due to the fact it would complicate the frequency coordination process.⁷⁴ AHA states that in-home uses of WMTS equipment are likely to be transient, both in terms of geographic location and duration and it is concerned that the frequency coordinator will not be able to ensure its database will not become unreasonably cluttered from transient uses that soon become inactive.⁷⁵ AHA recommends that until health care providers, equipment manufacturers and the frequency coordinator gain experience in the frequency coordination process, the Commission should review the use of equipment in the WMTS bands for in-home uses on a case-by-case basis. MedStar recommends a prohibition against home use of WMTS, although it believes the Commission should be willing to grant waivers on a case-by-case basis.⁷⁶ AHA, CDRH and Vitalcom all believe that the Commission should express a willingness to revisit this issue in a future proceeding.⁷⁷

31. Although many commenters support including mobile or in-home use of medical telemetry equipment under WMTS, the record does not clearly demonstrate that such uses can easily be accommodated. It would be difficult to ensure that the frequency of the WMTS equipment used on an ambulance would not conflict with the frequencies used at all the various hospitals and health care facilities in a given area, which could possibly result in interference. The temporary use of WMTS at many dispersed locations would make it difficult to coordinate their operating frequencies. We concur with AHA that home use may complicate coordination and that experience is required prior to allowing unrestricted home use. Accordingly, we decline to allow the use of the WMTS at home or in moving vehicles at this time, although we may revisit the issue of home use at a future date. While we will not rule out waivers to allow home use of WMTS, we believe that a hard look at such requests would be necessary due to interference concerns.

32. Frequency coordination. The comments supported our proposal to designate a frequency coordinator to maintain a database of all WMTS equipment identified by location, operating frequency, emission type and output power. NTIA notes that a frequency coordinator would facilitate band sharing between hospitals and the remaining government operations at protected sites.⁷⁸ Accordingly, we are adopting the proposal to designate a frequency coordinator to maintain a database of WMTS equipment. Without a database, there would be no record of WMTS usage because WMTS transmitters will not be individually licensed. The database will provide a record of the frequencies used by each facility or device to assist parties in selecting frequencies to avoid interference. The database will be used by eligible users and manufacturers

⁷² See Spacelabs comments at 8 and Zymed comments at 2.

⁷³ See ACCE reply comments at 2.

⁷⁴ See Vitalcom comments at 13.

⁷⁵ See AHA comments at 16.

⁷⁶ See MedStar comments at 9.

⁷⁷ See AHA comments at 16, CDRH comments at 4, and Vitalcom comments at 13.

⁷⁸ See NTIA comments at 1.

to plan for specific frequency use within a geographic area, especially where numerous WMTS operations may occur.

33. The frequency coordinator will not be a decision maker as to which frequency should be used. Rather, the coordinator will notify users of potential frequency conflicts, and users should be able to resolve any conflicts among themselves. We expect that there will be few conflicts between users of WMTS equipment due to its low operating power, but the Commission will make the final decision on a case-by-case basis in disputes between users, if necessary. The coordinator must be familiar with the medical telemetry user community, and must make its services available to all parties on a first-come, first-served and non-discriminatory basis. The frequency coordinator must be willing to serve a five-year term, which could be renewed by the Commission. In the event that a frequency coordinator does not wish to continue at the end of its term, it will have to transfer its database to another designated entity.

34. The *Notice* asked for comments on the following questions about the frequency coordinator: 1) any other qualifications that a frequency coordinator must have, 2) whether a single entity or multiple entities should be designated as frequency coordinator(s), 3) how the frequency records could be maintained with multiple coordinators, and 4) whether we should limit the fees the frequency coordinator(s) can charge.

35. Final Analysis, IIT and IAFC/IMSA all believe that a single frequency coordinator should be designated.⁷⁹ IIT stated that there is no advantage and many disadvantages to partitioning the database among multiple coordinators.⁸⁰ IAFC/IMSA does not believe Commission should limit fees charged by coordinator, stating that it would be difficult for the Commission to determine the appropriate fee and that it has not been necessary to impose fee limits on coordinators for other services operating under our Part 90 rules.⁸¹ IIT believes that costs should be recouped on a "cost-plus-fixed-fee" basis, and that cost ceilings could be set.⁸²

36. Several entities expressed an interest in being a frequency coordinator for WMTS.⁸³ Further, in the past the Commission has tried, where appropriate, to introduce market forces into the frequency coordination process.⁸⁴ Therefore, rather than adopt a Commission rule restricting database management of WMTS spectrum to a single coordinator, we will leave the ultimate decision on the number of coordinators up to the Commission's Wireless Telecommunications Bureau (WTB). WTB already has delegated authority to select frequency coordinators in the services it administers.⁸⁵ WTB will announce its coordination selection procedures in a Public Notice in the near future. We have not found it necessary to set limits on the fees charged by

⁷⁹ See *Final Analysis* comments at 36, IIT comments at 4, and IAFC/IMSA comments at 4.

⁸⁰ See *IIT* comments at 4.

⁸¹ See *IAFC/IMSA* comments at 4-5.

⁸² See *IIT* comments at 5.

⁸³ Five parties expressed an interest in becoming frequency coordinator for the WMTS. They are AHA, Comsearch, IIT, IAFC/IMSA and PCIA.

⁸⁴ See *Replacement of Part 90 by Part 88 to Revise the Private Land Mobile Radio Services and Modify the Policies Governing Them and Examination of Exclusivity and Frequency Assignment Policies of the Private Land Mobile Radio Services*, PR Docket 92-235, *Second Report and Order*, 12 FCC Rcd 14307 (1997).

⁸⁵ See 47 C.F.R. § 0.131(m).

coordinators in other services, and we have no reason to believe that fee limits will be necessary in the WMTS. Accordingly, we will allow the designated coordinator to set the fee structure as necessary to recoup costs.

37. The *Notice* proposed that certain information be submitted to the frequency coordinator for inclusion on the database, including:

- 1) frequency range(s) used
- 2) modulation scheme used
- 3) effective radiated power
- 4) number of transmitters in use at the health care facility at the time of registration
- 5) legal name of the authorized health care provider
- 6) location of transmitter (coordinates, street address, building)
- 7) point of contact for the authorized health care provider.

38. CDRH believes that the database should also include the makes and model numbers of equipment, and the fax numbers and e-mail addresses of the users.⁸⁶ IIT believes the database should also have fields for assigned frequencies, occupied bandwidth, manufacturer and model number, and equipment susceptibility.⁸⁷ IAFC/IMSA generally agrees with the information to be collected, but it is concerned that disclosure of the name of the health care provider and point of contact could be misused for commercial purposes and that it raises issues of the privacy of patient information.⁸⁸

39. We find that including the equipment manufacturer and model number in the database could be useful for helping the frequency coordinator and users in determining the interference potential of WMTS equipment.⁸⁹ This information could also assist the Commission or the FDA in locating certain devices in the event a question of compliance with the rules arose. Accordingly, we will specify that the equipment manufacturer and model number be submitted to the frequency coordinator for inclusion on the database. Much of the other information recommended by CDRH and IIT (fax numbers, e-mail addresses, assigned frequencies and occupied bandwidth) simply represents a more detailed description of the information we proposed. We agree with these recommendations and are including them in the final rules. We recognize that including the name of the health care provider and point of contact in the database could possibly make that information available to commercial entities. However, we find that this information is necessary to allow the coordinator and parties using the WMTS to contact other users to verify information and resolve potential conflicts. Thus, we will require the name of the health care provider and a point of contact to be included on the database. Including this information should not raise issues of privacy of patient information, because the database will not contain the patient names or other patient identification information. However, we disagree

⁸⁶ See CDRH comments at 5.

⁸⁷ See IIT comments at 6.

⁸⁸ See IAFC/IMSA comments at 6-7.

⁸⁹ We note that medical telemetry equipment is operated as a system, and that there may be many individual units with the same model number within a system. We are not requiring users to submit serial numbers or a separate registration for each individual unit in a system. Rather, the registration information submitted to the coordinator will indicate the quantity of each model or type of equipment used in the system.

with the suggestion of IIT to include information about equipment susceptibility. IIT did not specify exactly what type of information should be included, and in any case the Commission does not have clear authority to establish standards for the susceptibility of medical telemetry equipment.⁹⁰

40. We proposed that equipment registrations be effective until the health care provider requests their cancellation, and that access to the database be made available to all parties.⁹¹ We proposed that health care providers would have to notify the frequency coordinator when a system is permanently taken out of service, unless it is replaced with one with the same technical characteristics.⁹² We also proposed that health care providers notify the frequency coordinator of a change in the location of equipment to another facility or changes to other operating parameters of equipment.⁹³

41. AHA, MedStar and Vitalcom believe that equipment registrations should remain in the database until affirmatively removed, and that the database should be open to all parties.⁹⁴ However, Brian Porras, IIT and IAFC/IMSA believe that there should be an expiration date on database entries, which could prevent the database from becoming “cluttered” with out-of-date entries.⁹⁵ IIT recommends a ten year renewal period, and IAFC/IMSA recommends a five year renewal period, with the coordinator notifying users of the expiration of their registrations before deleting entries.⁹⁶ CDRH believes that the information on the database should be restricted to government agencies and those parties with needs for it that are related to health care.⁹⁷

42. We find that requiring periodic equipment registration renewals from health care providers to be an unnecessary burden. Most hospitals would find it difficult to remember to renew their registrations after five years have passed, and requiring coordinators to send out periodic renewal notices and process renewal applications could significantly increase their workload. However, we will not preclude coordinators from verifying the continued use of registered equipment on an “as needed” basis, such as when the database shows a conflict between a registered user and a new user. Accordingly, we are adopting our proposal that equipment registrations will remain valid until the health care provider requests cancellation. Restricting access to the database to certain parties would be difficult and burdensome for the coordinator because the coordinator would have to verify that each and every party accessing the database has a need for the information that is related to health care. Such restrictions could make it difficult for parties with legitimate needs for information to view the database. We therefore find that the database should be open to all parties.

⁹⁰ The Commission only has specific authority under the Communications Act to establish minimum performance standards for home electronic equipment and systems to reduce their susceptibility to interference from radio frequency energy. *See* 47 U.S.C. § 302(a).

⁹¹ *See Notice* at para. 32.

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *See AHA* comments at 17-19, *MedStar* comments at 10-11, and *Vitalcom* comments at 14-15.

⁹⁵ *See Brian Porras* comments at 2, *IIT* comments at 6, and *IAFC/IMSA* comments at 7.

⁹⁶ *See IIT* comments at 6 and *IAFC/IMSA* comments at 7.

⁹⁷ *See CDRH* comments at 5.

43. Permissible communications. We proposed that the WMTS could be used for all types of communications, except for voice or video transmissions.⁹⁸ We proposed to exclude these types of transmissions because we were concerned that video could occupy a significant portion of the spectrum allocated to the WMTS, and that allowing voice transmissions could encourage the equipment to be used as a form of wireless intercom.

44. AHA, MedStar and Vitalcom generally agreed with prohibiting voice and video transmissions in the WMTS bands, provided this prohibition does not include waveform information.⁹⁹ AHA believes that the Commission should be willing to revisit this issue at a later date, and MedStar believes that the Commission should consider allowing voice transmissions upon a special showing that such transmissions are consistent with the intended purpose of transmitting vital patient data.¹⁰⁰ Brian Porras disagreed with prohibiting voice and video transmissions and stated that there are other systems far more suitable for use as a wireless intercom.¹⁰¹ CDRH, OAT and Zymed all believe that the Commission should allow voice and video transmissions.¹⁰² CDRH states that the ability to send audio or medical images could augment the capabilities of the WMTS.¹⁰³

45. We find that the transmission of waveform information such as electrocardiograms (ECGs) is within the intended purpose of the WMTS, which is to transmit vital patient data. Accordingly, we will permit the transmission of waveform information in the WMTS. However, allowing the general purpose use of video in the WMTS could potentially result in video occupying a large portion of the available spectrum. This is a greater concern initially because portions of the WMTS spectrum will be unavailable for a number of years in parts of the country due to grandfathered government operations. We are not persuaded that there is currently a need for voice capabilities in telemetry equipment, and we reiterate our concern that allowing such capabilities could encourage use of the equipment for other than its intended purpose of transmitting patient data. Accordingly, we will prohibit voice and video transmissions in the WMTS at this time, but we may revisit the issue at a later date after government operations cease in the WMTS bands.

46. Technical Standards. We proposed only minimal technical standards for WMTS equipment to give manufacturers the flexibility to develop different applications for medical telemetry. We did not propose a specific channelization scheme for the 1395-1400 MHz and 1429-1432 MHz bands. However, to prevent users from monopolizing the 608-614 MHz band, we proposed that equipment using broadband technologies, such as spread spectrum, be capable of operating on channels of 1.5 MHz each, up to a maximum of 6 MHz.¹⁰⁴ Such equipment would operate on the minimum number of channels necessary, and must have the capability of being "throttled back" so it will occupy as little as one 1.5 MHz channel, if necessary, to allow multiple users to share that band. There were no objections to the proposed requirement on maximum channel usage in the 608-614 MHz band, so we are adopting this requirement which will allow the

⁹⁸ See Notice at para. 33.

⁹⁹ See AHA comments at 19-20, MedStar comments at 12, and Vitalcom comments at 17.

¹⁰⁰ See AHA comments at 20 and MedStar comments at 13.

¹⁰¹ See Brian Porras comments at 2.

¹⁰² See CDRH comments at 5, OAT comments at 2, and Zymed comments at 3.

¹⁰³ See CDRH comments at 5.

¹⁰⁴ See Notice at para. 35.

WMTS spectrum to be used more efficiently. We believe that stringent spectrum efficiency standards are unnecessary due to the highly competitive nature of the manufacturing industry for wireless biomedical telemetry equipment. Regulatory flexibility will encourage competitive manufacturers to innovate and to use more efficient technologies to meet future medical health care demands. We do not contemplate allocating additional spectrum for the WMTS. It is therefore incumbent on manufacturers and WMTS users to be spectrum efficient in the design and use of WMTS equipment.

47. We proposed the following field strength limits for transmitters in the WMTS.¹⁰⁵

Frequency band	Maximum field strength	Measurement Distance	Measurement Bandwidth	Detector Function
608-614 MHz	200 mV/m	3 meters	120 +/- 20 kHz	CISPR QP
1395-1400 MHz	740 mV/m	3 meters	1 MHz	Average
1429-1432 MHz	740 mV/m	3 meters	1 MHz	Average

48. The limit we proposed in the 608-614 MHz band was lower than the limit proposed by AHA in their report.¹⁰⁶ AHA, Datascope, IIT, Martha McDonough, Vitalcom and Zymed all requested that the Commission adopt the higher limit proposed by AHA.¹⁰⁷ AHA stated that the higher limit is necessary to allow WMTS equipment to overcome the noise levels typically found in hospitals.¹⁰⁸ Datascope, Martha McDonough and Vitalcom stated that higher limits can help reduce the cost and complexity of medical telemetry systems, and IIT stated higher limits would improve the systems' reliability.¹⁰⁹ However, HP believes that the limit we proposed is sufficient to address the severe noise and fading found in hospitals, and that the losses due to fading can be addressed more effectively through system design and antenna placement than through increased transmitter power.¹¹⁰ The National Academies and NTIA supported our proposed limit because it will protect radio astronomy operations from interference.¹¹¹

49. The current field strength limit in the 608-614 MHz band was developed after consultations between the Commission, NTIA and radio astronomy interests. The limit was selected to allow a reasonable operating level for medical telemetry equipment while still protecting radio astronomy operations from interference. We recognize that there could be certain benefits to medical telemetry users with a higher limit in this band, but as HP notes, the current limit is adequate with proper system design. In the interest of protecting radio astronomy operations, we

¹⁰⁵ See Notice at para. 36.

¹⁰⁶ AHA proposed a limit of 370 mV/m at 3 meters in the 608-614 MHz band, which is approximately 5 dB higher than the limit in Part 15. See 47 C.F.R. § 15.242.

¹⁰⁷ See AHA comments at 21, Datascope comments at 2, IIT comments at 7, Martha McDonough comments at 1, Vitalcom comments at 17-18, and Zymed comments at 3.

¹⁰⁸ See AHA comments at 21.

¹⁰⁹ See Datascope comments at 2, Martha McDonough comments at 1, Vitalcom comments at 18, and IIT comments at 7.

¹¹⁰ See HP comments at 2-3.

¹¹¹ See National Academies comments at 3 and NTIA reply comments at 1.

will apply a limit of 200 mV/m measured at 3 meters to medical telemetry equipment in the 608-614 MHz band. There were no objections to the proposed limits in the 1395-1400 MHz and 1429-1432 MHz bands, and we are adopting them as proposed.

50. We proposed the same out-of-band field strength limits for transmitters in the WMTS bands that are used for most intentional radiators under Part 15 of the rules.¹¹² We have found those limits to be effective at controlling interference. There were no objections to applying the Part 15 out-of-band emission limits to WMTS equipment, and we are adopting them.

51. Protection of other existing services. The WMTS must not cause interference to radio astronomy operations, and to certain grandfathered government operations. We are therefore adopting rules requiring the coordination of WMTS operations in the 608-614 MHz band with radio astronomy operations, which are the same as the coordination requirements currently found in Part 15.¹¹³ The rules also require operators in the 1395-1400 MHz and 1429-1432 MHz bands to protect certain government operations. Finally, parties using WMTS equipment should be aware that the operation of transmitters in close proximity to medical equipment could cause interference to the operation of the medical equipment. The rules provide a warning to this effect, which is the same warning found in Part 15.¹¹⁴

52. RF Safety. We do not currently require the routine evaluation of medical telemetry equipment for compliance with the radiofrequency (RF) radiation safety guidelines in our rules due to the low power of the equipment.¹¹⁵ The *Notice* did not propose to require RF safety measurements for WMTS equipment because such equipment would also operate at relatively low power levels. However, PCTEST stated in its comments that WMTS equipment operating under the proposed technical parameters could exceed the RF safety guidelines.¹¹⁶ It therefore recommends that the Commission require measurements of the specific absorption rate (SAR) of RF energy by the body from WMTS equipment. AHA disagrees with PCTEST stating that the Commission already excludes other devices from RF exposure measurements that have similar power and operating frequencies to WMTS. Further WMTS devices will have to be approved by the FDA, which evaluates the safety and effectiveness of all medical devices.¹¹⁷

53. Our rules for RF safety classify equipment into two categories: 1) mobile devices, which normally operate with at least a 20 centimeter separation from the radiating element to the body of the user or a nearby person¹¹⁸, and 2) portable devices, which normally operate with less than a 20 centimeter separation from the radiating element to the body of the user.¹¹⁹ Based upon our analysis, we agree with PCTEST that portable WMTS equipment could possibly exceed the RF

¹¹² See 47 C.F.R. § 15.209.

¹¹³ See 47 C.F.R. § 15.242(e).

¹¹⁴ See 47 C.F.R. § 15.242(h).

¹¹⁵ The rules require the routine evaluation of certain mobile and portable equipment for compliance with RF radiation safety guidelines. Medical telemetry equipment is not covered by these requirements. See 47 C.F.R. §§ 2.1091(c) and 2.1093(c).

¹¹⁶ PCTEST also filed ex-parte comments addressing the RF safety of WMTS equipment.

¹¹⁷ See AHA reply comments at 17.

¹¹⁸ See 47 C.F.R. § 2.1091(b).

¹¹⁹ See 47 C.F.R. § 2.1093(b).

safety guidelines in our rules. Accordingly, we will require routine environmental evaluation for RF exposure of portable WMTS equipment prior to equipment authorization or use. We expect that the majority of WMTS equipment will be classified as “portable” because medical telemetry transmitters are typically worn on the body. However, we realize that there may be some applications where the transmitter is separated from the body by more than 20 centimeters, such as a unit mounted on a bed or incorporated within a separate device. Consistent with the RF safety requirements for other services, mobile WMTS equipment will be categorically excluded from routine environmental evaluation because WMTS equipment complying with the technical requirements we are adopting will operate with an effective radiated power (ERP) of less than 1.5 watts, which is the threshold for the exclusion of equipment operating below 1.5 GHz.¹²⁰

54. Equipment authorization requirement. The *Notice* proposed authorizing WMTS transmitters through the Declaration of Conformity (DoC) procedure in Part 2 of the rules.¹²¹ DoC is a manufacturer's self-approval procedure where the equipment is tested to ensure it complies with the Commission's technical standards, and may then be marketed without an approval by the Commission. Final Analysis and IIT agreed that WMTS transmitters should be authorized under the DoC procedure.¹²² However, PCTEST believes the Commission should require certification for WMTS equipment because no specific measurement procedure exists, and because there is little or no guidance for equipment setup, measurement equipment or test sites above 1 GHz.¹²³ In an *ex-parte* filing, Phillip Inglis also stated that WMTS equipment should be subject to certification due to measurement uncertainties and the need to make SAR measurements.¹²⁴ AHA disagrees with PCTEST that WMTS equipment should be subject to certification because the certification process just creates delays for manufacturers.¹²⁵

55. The certification procedure requires the manufacturer to file electronically a test report showing the equipment complies with the rules along with other supporting documentation to the Commission or to a designated Telecommunication Certification Body (TCB).¹²⁶ The equipment may not be marketed until an approval has been received from the Commission or a TCB. Upon further consideration, we agree that certification is the appropriate authorization procedure for WMTS equipment. WMTS equipment involves new technologies, and the majority will be subject to routine environmental evaluation for RF safety.¹²⁷ Requiring certification is consistent with the actions we have taken in similar cases, such as the Medical Implant Communication Service (MICS) in Part 95.¹²⁸ However, we note that procedures for making the RF exposure measurements are currently under development. When such procedures are developed, we may consider relaxing the certification requirement for medical telemetry equipment.

¹²⁰ See 47 C.F.R. § 2.1091(c).

¹²¹ See 47 C.F.R. § 2.1071, et. seq.

¹²² See *Final Analysis* comments at 39 and *IIT* comments at 8.

¹²³ See *PCTEST* comments at 7.

¹²⁴ See *Phillip Inglis ex parte* filing at 3.

¹²⁵ See *AHA* reply comments at 16-18.

¹²⁶ See 47 C.F.R. § 2.1031, et. seq.

¹²⁷ See § 95.1125 RF Safety in Appendix A.

¹²⁸ See *Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band*, 14 FCC Rcd 21040 (1999).

C. Transition Provisions

56. Equipment authorization. We proposed that all new medical telemetry equipment that receives an equipment authorization starting two years after the adoption of final rules must operate in the newly authorized frequency bands.¹²⁹ We also proposed that medical telemetry equipment that has received an equipment authorization to operate in the old bands prior to that date may continue to be manufactured, imported, marketed and operated indefinitely.¹³⁰ IIT, Spacelabs and Vitalcom agreed with the proposed two year transition period for new equipment.¹³¹ AHA, GE and Medstar agree that new equipment should have the capability of operating in the new bands, but believe that we should allow “dual-mode” equipment with the capability of operating in the current Part 15 and Part 90 bands in addition to the new bands.¹³² GE states that this would provide for the instances in which the new primary frequencies may not be usable or may not afford sufficient capacity.¹³³

57. Two years is a reasonable timetable for requiring manufacturers to produce equipment to operate in the new bands. Based on the comments received, we are confident that manufacturers will be able to meet this deadline. We decline to allow equipment approved after that deadline to have the capability of operating in the current Part 15 and Part 90 bands. Our goal in this proceeding is to not only provide spectrum where medical telemetry equipment can operate without interference, but also to encourage medical telemetry users to eventually migrate out of the current bands. Despite the fact that medical telemetry has no legal protection from interference in these bands, the fact remains that the Commission has had to take steps to protect medical telemetry from interference because it is used to protect safety of life. The steps the Commission has taken, such as the freeze in the 450-470 MHz band and the requirement for DTV stations to notify nearby health care facilities, affect other parties. We therefore wish to encourage medical telemetry users to migrate out of the current frequency bands and into the new frequency bands. Allowing the development of new equipment that can operate in the old bands after the transition date would discourage the eventual migration to the new bands.

58. Grandfathering. AHA believes that the Commission should grandfather the continued use and production of lawfully manufactured equipment in the Part 15 and Part 90 bands.¹³⁴ IIT believes that there is no need to set a cutoff for equipment operating under Parts 15 and 90 since it is unlicensed and operates at the risk of the user.¹³⁵ Medstar believes that the use of devices manufactured and in operation by the transition deadline should be permanently grandfathered, and the manufacture of devices authorized before the transition deadline should be grandfathered.¹³⁶ Spacelabs urges the Commission to grandfather equipment currently authorized under Parts 15 and

¹²⁹ See Notice at para. 41.

¹³⁰ Id.

¹³¹ See IIT comments at 8, Spacelabs comments at 3, and Vitalcom comments at 19.

¹³² See AHA comments at 23, GE comments at 11, and MedStar comments at 14.

¹³³ See GE comments at 1.

¹³⁴ See AHA comments at 23.

¹³⁵ See IIT comments at 8.

¹³⁶ See MedStar comments at 14.

90 that is purchased within 2 years after finalization of current rule making.¹³⁷ Vitalcom believes that the Commission should grandfather the continued use and production of wireless medical telemetry equipment lawfully manufactured for the Part 15 band.¹³⁸

59. Requiring the replacement of functional medical telemetry systems that are not subject to interference would be an unnecessary financial burden on hospitals. Accordingly, we will permit medical telemetry equipment that has received an equipment authorization to operate in current Part 15 and Part 90 bands prior to the two year transition date to be manufactured, imported, marketed and operated without a cutoff date.¹³⁹ This action will ensure that manufacturers will be able to make replacement parts for systems operating in the old bands, and that hospitals will be permitted to operate their existing systems as long as possible until replacement is necessary due to age or interference concerns.

60. Existing equipment registration. AHA believes that the Commission should allow the voluntary registration of existing Part 15 medical telemetry devices in the database.¹⁴⁰ LMCC and PCIA want the Commission to mandate the registration of medical telemetry equipment in the land mobile bands so land mobile operators can avoid them during the transition period.¹⁴¹ ACCE and AHA do not oppose the registration of equipment in the 450-470 MHz band, but considers the LMCC proposal to be unworkable.¹⁴²

61. We find it unlikely that a complete database of all Part 15 and Part 90 medical telemetry transmitters could be developed prior to the transition to the new frequency bands. However, placing even some transmitters in a database could possibly assist parties in avoiding cases of interference. We therefore have no objection to allowing the voluntary registration of existing Part 15 and Part 90 medical telemetry devices. The rules we are adopting allow frequency coordinators to process voluntary requests to register equipment operating under Parts 15 and 90.

D. 450-470 MHz Freeze

62. In 1995, the Commission adopted changes to Part 90 of the rules to allow more efficient use of the spectrum for land mobile services.¹⁴³ These changes permitted high power operations on channels in the 450-470 MHz band. However, under the new channeling scheme, high-power primary users of the band would be able to operate on the same frequencies used for medical telemetry equipment. This could possibly result in interference to medical telemetry

¹³⁷ See Spacelabs comments at 4.

¹³⁸ See Vitalcom comments at 19.

¹³⁹ These transition provisions apply only to in-hospital medical telemetry equipment. Ambulance-to-hospital medical telemetry equipment may continue to operate under the provisions of Part 90 of the Rules.

¹⁴⁰ See AHA comments at 15.

¹⁴¹ See LMCC comments at 11 and PCIA comments at 8.

¹⁴² See ACCE reply comments at 1 and AHA reply comments at 15.

¹⁴³ See Replacement of Part 90 by Part 88 to Revise the Private Land Mobile Radio Services and Modify the Policies Governing Them and Examination of Exclusivity and Frequency Assignment Policies of the Private Land Mobile Radio Services, PR Docket 92-235, Report and Order and Further Notice of Proposed Rule Making (Refarming R&O), 10 FCC Rcd 10076 (1995).

equipment. For this reason, on August 11, 1995, the Commission placed a freeze on the filing of applications for high power operation in the 450-470 MHz band on the 12.5 kHz offset channels.¹⁴⁴

63. 450-460 MHz band freeze. On October 20, 1999, the Commission issued a public notice asking parties operating medical telemetry equipment in the 450-460 MHz band to provide certain information to the Commission.¹⁴⁵ We received responses from 25 parties around the country operating in this band. The majority of these users were operating a small number of devices on a limited number of frequencies around 457 and 458 MHz. Based on the limited usage of the 450-460 MHz band for medical telemetry, we find that the freeze on high-power land mobile applications in the 450-460 MHz band can be lifted. Accordingly, the Wireless Telecommunications Bureau will issue a public notice announcing the lifting the freeze in this band in the near future. We will work closely with the FDA to inform and educate the medical community of the lifting of the freeze to avoid interference to medical telemetry equipment.

64. 460-470 MHz band freeze. AHA and Spacelabs believe that a minimum five year transition period is necessary before lifting the freeze on high-power land mobile applications in the 460-470 MHz band.¹⁴⁶ AHA objects to proposals to shorten the transition period for equipment in the 460-470 MHz band because sufficient spectrum is not immediately available for migration in all locations and replacement costs can not be absorbed by health care facilities in less than five years.¹⁴⁷ Spacelabs wants a one-year transition period before lifting the freeze in the 450-460 MHz band.¹⁴⁸ Brian Porras and CDRH support a four-year transition period to allow manufacturers and healthcare facilities adequate time to make the transition in an orderly manner.¹⁴⁹ Brian Porras stated that hospitals are struggling financially and can't afford a major capital expenditure in a shorter timeframe to convert their equipment.¹⁵⁰ However, AMTA, LMCC, Motorola and PCIA believe that AHA's proposed transition period can be shortened.¹⁵¹ LMCC, Motorola and PCIA state that medical telemetry could move to either the 608-614 MHz band or one of the designated low power channels in the 1997 LMCC low power plan.¹⁵²

65. We find that a five-year transition period is longer than is necessary to prepare for the lifting of the freeze in the 460-470 MHz band. The freeze was announced almost five years ago, so

¹⁴⁴ See *Public Notice, "Freeze on the Filing of High Power Applications for 12.5 kHz Offset Channels in the 450-470 MHz Band,"* released August 11, 1995, 10 FCC Rcd 9995 (1995).

¹⁴⁵ See *Public Notice, Office of Engineering and Technology Requests Information on Medical Telemetry Equipment Operating in the 450-460 MHz Band*, DA 99-2244, released October 20, 1999, available at www.fcc.gov/Bureaus/Engineering_Technology/Public_Notices/1999/da992244.html. The deadline specified in this public notice was subsequently extended to March 31, 2000. See *Public Notice, Office of Engineering and Technology Extends Deadline for Submitting Information on Medical Telemetry Equipment Operating in the 450-460 MHz Band until March 31, 2000*, available at www.fcc.gov/Bureaus/Engineering_Technology/Public_Notices/2000/.

¹⁴⁶ See AHA comments at 25 and Spacelabs comments at 4.

¹⁴⁷ See AHA reply comments at 20.

¹⁴⁸ See Spacelabs comments at 5.

¹⁴⁹ See Brian Porras comments at 2 and CDRH comments at 6-7.

¹⁵⁰ See Brian Porras comments at 2.

¹⁵¹ See AMTA comments at 5, LMCC comments at 12, Motorola comments at 4 and PCIA comments at 6.

¹⁵² See LMCC comments at 12, Motorola comments at 5, and PCIA comments at 6.

hospitals have been on notice that they may eventually have to change frequencies. Equipment is already available to operate in the 608-614 MHz band we are allocating in this proceeding, and equipment to operate in the other bands allocated in this proceeding should become available over the next two years. Five more years should not be required for hospitals to make the transition. We will therefore lift the freeze on high power land mobile application in the 460-470 MHz band within three years from the effective date of final rules in this proceeding. We will work closely with the FDA to inform and educate the medical community of the impending lifting of the freeze to accelerate this process.

E. Other Matters

66. ISM bands. A small number of medical telemetry devices operate in the Industrial, Scientific and Medical (ISM) bands under provisions in Part 15 of the rules.¹⁵³ These provisions are not specific to medical telemetry equipment, and any type of low power transmitter may be approved to operate under these sections, including cordless telephones, video transmitters and wireless modems. The *Notice* did not propose to prohibit medical telemetry equipment from operating under these sections. Symbol and Criticare both want the Commission to clarify whether medical telemetry will continue to be permitted to operate under these provisions.¹⁵⁴ Mortara is concerned that dedicated bands for medical telemetry may create confusion for users that equipment in the ISM bands is unapproved, inappropriate, or outside of “standards”.¹⁵⁵

67. The *Notice* did not propose to preclude medical telemetry equipment from operating in the ISM bands under Part 15 because only a small number of devices operate under these provisions. Therefore, there is not the same potential for a large number of cases of interference to medical telemetry equipment in these bands as there is for medical telemetry equipment operating in the TV and PLMR bands. We expect that the majority of medical telemetry equipment manufacturers will design equipment for the new bands allocated in this proceeding, and that only a small number of devices will continue to use the ISM bands. Therefore, we will continue to allow medical telemetry equipment to operate in the ISM bands under Part 15. While such operation will be permissible, manufacturers and users are cautioned that equipment operating in these bands has no protection from interference from ISM equipment operating under Part 18 of the rules or other low power transmitters operating under Part 15 of the rules.

ADMINISTRATIVE MATTERS

68. Final Regulatory Flexibility Analysis. The Final Regulatory Flexibility Analysis for this Report and Order, pursuant to the Regulatory Flexibility Act, 5 U.S.C. § 604, is contained in Appendix C.

¹⁵³ Industrial, Scientific and Medical (ISM) equipment uses radiofrequency energy to perform work rather than for a communication purpose. Examples of ISM equipment include microwave ovens and certain industrial heating and welding equipment. A number of bands are available for ISM equipment under Part 18 of the rules. See 47 C.F.R. § 18.301. Low power transmitters are permitted to operate in certain ISM bands under Part 15 of the rules. See 47 C.F.R. §§ 15.247 and 15.249.

¹⁵⁴ See Symbol comments at 2 and Criticare comments at 1.

¹⁵⁵ See Mortara comments at 2.

69. Paperwork Reduction Act Analysis. This Report and Order contains (either new or modified) information collection(s) subject to the PRA of 1995, Public Law 104-13. It will be submitted to the Office of Management and Budget (OMB) for review under Section 3507(d) of the PRA. OMB, the general public, and other Federal agencies are invited to comment. Public and agency comments are due **[insert date 60 days after date of publication in the Federal Register.]** Comments should address: (a) whether the new or modified collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

70. To make cited sources more easily available to the readers, we are testing the use of hyperlinks to some FCC documents that are cited in this document. The World Wide Web addresses/URLs that we give here were correct at the time this document was prepared but may change over time. We do not have dedicated staff to update these URLs, however, so readers may find some URLs to be out of date as time progresses. We also advise that the only definitive text of FCC documents is the one that is published in the FCC Record. In case of discrepancy between the electronic documents cited here and the FCC Record, the version in the FCC Record is definitive. (Most word processors will allow users to "click through" to URLs in the electronic version of this document. However, some installations may preclude direct access to URLs with long character strings. In this case other techniques should be used to access the given URLs.)

ORDERING CLAUSES

71. IT IS ORDERED, that Parts 2, 15, 90 and 95 of the Commission's Rules and Regulations ARE AMENDED as specified in Appendix A **[effective 90 days after publication in the Federal Register]**. This action is taken pursuant to Sections 4(i), 11, 301, 302, 303(e), 303(f), 303(r), 304, 307 and 332(b) of the Communications Act of 1934, as amended, 47 U.S.C. Sections 154(i), 161, 301, 302, 303(e), 303(f), 303(r), 304, 307 and 332(b).

72. IT IS FURTHER ORDERED that the Commission's Consumer Information Bureau, Reference Information Center, SHALL SEND a copy of this Report and Order, including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

73. IT IS FURTHER ORDERED that ET Docket 99-255 is terminated.

74. For further information regarding this Report and Order, contact Hugh L. Van Tuyl, (202) 418-7506, Office of Engineering and Technology.

FEDERAL COMMUNICATIONS COMMISSION

Magalie Roman Salas
Secretary